K001942

JUL 2 5 2000

K001942
Special 510(k)
SL-PLUS® and SLR-PLUS® Stems
July 10, 2000

510(k) Summary of Safety and Effectiveness

Contact: Hartmut Loch, C.E.O.
PLUS ORTHOPEDICS
3550 General Atomics Ct., Bldg. 15-100
San Diego, CA 92121
Tel: 858-455-2400

Trade name: SL-PLUS® and SLR-PLUS® Stems

Common name: Total Hip Joint, Femoral Component, Cementless

Classification name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
21 CFR 888.3350 (87 LWJ)

Equivalence: SL-PLUS® and SLR-PLUS® Stems, K932481, S/E 06/08/94

Characteristics: The SL-PLUS® and SLR-PLUS® Femoral Stems are of a double taper design and are manufactured from Ti-6Al-7Nb titanium alloy according to ASTM F136-98. The primary stem SL-PLUS® is available in 14 sizes ranging from size 01 through 12. The SLR-PLUS® revision stem is available in 11 sizes ranging from size 1 through 11. The femoral ball heads are manufactured from CoCrMo alloy according to ASTM F799-99. They are available in 22 mm, 28 mm, and 32 mm diameters and five different lengths, namely small (S), medium (M), long (L), extra long (XL) and extra-extra long (XXL). In addition, the INTRAPLANT ceramic ball heads with 28 mm and 32 mm diameter may be used with the SL-PLUS® and SLR-PLUS® stems.
PLUS Unipolar CoCrMo, K990309, S/E/ 3/15/99
PLUS Bipolar CoCrMo, K982447, S/E/ 11/25/98
INTRAPLANT Ceramic Head Prosthesis, K990261, S/E 8/27/99.

Indications: The SL-PLUS® Stem primary component is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SLR-PLUS® Stem, a revision component, is also available to replace previously failed femoral hip arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

Contraindications: Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.

Performance data: Biomechanical Testing has been done. All test results are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Mr. Hartmut Loch
Chief Executive Officer
Plus Orthopedics
Building 15-100
3550 General Atomics Court
San Diego, California 92121-1122

Re: K001942
Trade Name: SL-Plus® and SLR-Plus® Stems
Regulatory Class: II
Product Code: LWJ and JDI
Dated: June 23, 2000
Received: June 26, 2000

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001942

Device Name: SL-PLUS® and SLR-PLUS® Stems

Indications for Use:

The SL-PLUS® Stem primary component is intended for treating patients who are candidates for total hip arthroplasty because the natural femoral head and neck has been subject to disease or trauma. The SLR-PLUS® Stem, a revision component, is also available to replace previously failed femoral hip arthroplasties. Both components can be used with or without cement. These devices are intended to aid the surgeon in relieving the patient of hip pain and restoring hip motion.

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochines.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001942

Prescription Use yes
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use No
(Optional Format 1-2-96)